

U. S. Reissue Application

of

U.S. Patent No. 5,431,648, Issued July 11, 1995

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Title: RADIATING DEVICE FOR HYPERTHERMIA

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## BACKGROUND OF THE INVENTION

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This invention concerns a radiating device for hyperthermia and, more particularly, a radiofrequency radiating device, for hyperthermal treatment of tumors of the bladder.

Devices for hyperthermal treatment of various human body illnesses are already known, and they use heating liquids, light radiations, radiofrequency antennas, thermistors, and so on.

U.S. Pat. No. 4,776,334 describes a catheter for treating tumors by inserting within the tumor to be treated a radiofrequency device provided with temperature sensors.

French patent application 2600205 concerns an apparatus for light irradiation of a cavity with the help of an inflatable balloon and of light sensors.

In U.S. Pat. No. 4,154,246 there is described a radio-frequency resonating circuit which is introduced in natural cavities of the body or directly inserted into the tumoral mass.

German patent application No. 2,848,636 claims usage of a heated liquid which is circulated in a closed loop by means of a pump within a body cavity, wherein the liquid temperature is controlled by an external thermostat. EP-A-0 370 890 discloses a radiating urethral device for hyperthermia including a catheter provided with an inflatable balloon and adapted to receive one or more liquid flows passing therethrough, a radiofrequency radiating antenna, and one or more thermocouples, the radiating antenna being submerged within one said liquid flow coming back from the closed terminal end of the antenna. The radiating device comprises in addition a separate rectal control means.

GB-A-2 045 620 relates to an applicator for hyperthermia comprising a rectal radiating probe and a spaced apart transurethral catheter including a temperature sensing means and an inflatable balloon. U.S. Pat. No. 4,957,765 discloses a transurethral radiating applicator for hyperthermia including a multi-tubes balloon type catheter comprising closed and cubes respectively surrounding a helical coil antenna and a temperature sensor, as well as a passive drainage tube for urine.

It is an object of this invention to provide a device for hyperthermal treatment of tumors within natural cavities of the human body, which gathers the advantages of the known devices while being free from their drawbacks.

## SUMMARY OF THE INVENTION

The device according to this invention substantially comprises a flexible triple path catheter carrying a radiofrequency radiating antenna, sealingly sheathed together with the shielded cable providing power supply and with several thermocouples within a plastic casing and surrounded by a flow of liquid; a second path carries the power supply cables for several outer thermocouples, which are flooded by return flow of said liquid, and a third path allowing a fluid to flow through in order to inflate a balloon located near the catheter distal end, once the latter has been introduced into the cavity to be treated.

This invention will be described more particularly in 65 the following based on a specific embodiment thereof reported herein for exemplary and non limiting purposes, as well as on the attached schematic drawings. In

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows schematically, in an enlarged scale, the distal end of the device according to this invention, which has to be introduced into a natural cavity of the human body;

FIG. 1A shows an enlarged schematic cross-section of the device according to this invention, taken along line A—A of FIG. 1;

FIG. 2 is a schematic of some structural details of a radiofrequency antenna shown in general within the device of FIG. 1;

FIG. 2A shows a schematic enlarged cross-section of the radiating antenna, taken along line A—A of FIG. 2;

FIG. 3 is a schematic of the proximal end of the device according to this invention, opposite to the distal end shown in FIG. 1;

FIG. 4 is a plot of the intensity of the radiation generated by the radiating antenna of FIG. 2, along the longitudinal axis thereof;

25 FIG. 5 shows schematically the distal end of the device of FIG. 1, as it is seen after having been introduced into a urinary bladder; and

FIG. 6 shows schematically the structure at the distal end of the device shown in FIG. 1, when ready for introduction into the organ to be treated.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

The device according to this invention has a shape and consistency of a flexible catheter whose distal end, as it is shown in FIG. 1, encloses therewithin an antenna 1 surrounded by a flow of liquid 2 which is introduced into the bladder through an opening 3 and, after being freely circulated within said bladder, is again sucked into the catheter through an opening 4. Said opening 4 is in communication with a second way or catheter side channel 5 housing the leads of several thermocouples, like for instance 6, 6', 6'' adapted to be deflected outwards by inflating a balloon 7 in which a gaseous fluid or a liquid is made to flow through a third path or side channel 8 and through an end opening 9.

The catheter opposite (proximal) end (FIG. 3) whose tip is shown in FIG. 1, has three diverging inlets corresponding to the three paths or channels 2, 5, 8 of said catheter. Within center inlet 10 there is inserted with a pressure fit a plug 11 provided with a center through passage and with a side branch 13; in center passage 12 of plug 11 there is in turn pressure fitted a second plug 14 which is provided as well with a center opening 15. Shielded cable 16 supplying power to antenna 1 runs through the center passages 12 and 15 of said two coaxially arranged plugs, while side branch 13 is provided as an inlet and an outlet of a conditioning fluid flowing along channel 2. Thermocouple power supply cables 6, 6', 6'' are laid through side entrance 17 provided with a branch 18, and they run along side path or channel 5 having said conditioning liquid flowing in a reverse direction therethrough, said liquid entering and exiting in turn through said branch 18. The other side entrance 19 is provided with a one-way valve 20 for introducing the fluid that, flowing along second side channel 8, is used to inflate balloon 7.

FIG. 4 is a diagram showing the radiation intensity starting from the coil-shaped end 21 of antenna 1 towards shielded power supply cable 22, 16. As it is

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There is shown schematically in FIG. 5 the longitudinal section of the catheter provided with a radiating antenna according to this invention, once it has been introduced into the bladder, in an operative condition. The catheter, carrying the radiating antenna therewithin, is introduced into bladder 32 through the ure-

The dimensions of antenna 1 are such that it may be freely positioned along the catheter while being obviously wholly contained within the human bladder to be treated, but in the meantime they must be suitable to generate a therapeutically active radiation, in order to reach the temperatures considered lethal for the cancer cells. Since the physical length of an antenna is related to the virtual electrical length thereof through an equation involving the impedance of said antenna, as well as the impedance deriving from the environment irradiated by the antenna, the antenna electrical length comes out to be inversely proportional to the irradiated medium conductivity. Accordingly, since the conductivity of an aqueous solution is for instance many times higher than the conductivity of air, when operating in an aqueous environment it is possible to use an antenna which is

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The dipole according to this invention corresponds to a dipole of the quarter wave type and in the aqueous environment comprising the solution filled bladder, it makes it possible to operate at frequencies in the range of 900-1000 MHz; in particular, a frequency of 915 MHz has been chosen since very different frequencies would result in penetration, intensity, and other effects not always exactly predictable and controllable in the body tissues, since in general high frequencies have a low penetration power and therefore they do not provide the desired local heating, while lower frequencies, having a higher penetration power, may get deeper tissues involved and damaged.

On the other hand, radiations having different wavelengths might create a disturbance for radio and telephone communications, protected by constraints imposed by the legislations of the various countries.

In order to reduce to a minimum and possibly to nil the influence of the radiofrequency field on the thermocouples, as well as the various thermoelectric effects connatural with said thermocouples, the supply cable end stretches close to the thermocouples are wound into an helical shape whereby the temperature measured in the various sensing points is a reliable data, unaffected by said influences. The above structure construction prevents measuring errors due to conduction, it provides a reliable temperature indication, for instance exactly in the area of the dipole power supply position in the case of thermocouple 30, and it reduces in an extremely effective manner the thermocouple self-heating process due to radiofrequencies, also when there is an extremely high concentration of energy, whereby said structures are almost unaffected by the disturbances in the radio-frequency field.

Since the sizes, and in particular the cross-sections of the plural device components according to this invention must be extremely small, to suit the particular field of use desired for the device, the energy losses due for instance to self-heating of the antenna power supply cable are particularly high, for instance in the range of 20-40%. Since this undesirable self-heating, due to the Joule effect, might cause excessive heating of the urethral walls, and accordingly a discomfort for the patient subjected to treatment, or even damages to the tissues, the antenna cable, and the antenna itself are continuously cooled, while in operation, by using the conditioning liquid flow directed to the bladder and then withdraws again therefrom, whereby a simultaneous control action is obtained, for controlling the temperature prevailing both in the liquid within the bladder and along the urethra. Temperature control is effected by variations of the conditioning liquid supply flow and of the cooling source temperature. In such a way it is possible both to increase the temperature and to withdraw heat.

In order to enable outer thermocouples 6, 6', 6'' for detecting the bladder wall temperature to be safely deflected outwards when balloon 7 is inflated, the power supply cables thereof are reinforced along their whole length by inserting within the protecting sheath thereof a thin stainless steel wire providing them with the required rigidity and flexibility. The presence of said reinforcing wire provides as well the thermocouple power supply cables with the mechanical strength necessary to bear the compressive and tensile stresses caused when the cables are inserted within side channel

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55 It is pointed out herein that all the antenna and thermocouple components contacted by the liquid circulating within the bladder are sealingly lined and insulated from the outer environment by a polytetrafluoroethylene layer whereby, after each usage and application  
60 they may be sterilized for subsequent further use.